



In The United States Patent and Trademark Office

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6/27/00

OP 1648

In re Application of:

Assignee: Genentech, Inc.

Inventors: Phillip W. Berman et al.

Serial No.: 09/103,262

Filed: June 23, 1998

For: METHODS AND  
COMPOSITIONS FOR  
VACCINATION AGAINST  
HIV

Group Art Unit: 1648

Examiner: Budens, R.

Attorney Docket No.: 14918-725 CON4

Certificate of Mailing Under 37 C.F.R. § 1.8

Pursuant to 37 C.F.R. § 1.8, I hereby certify that this paper and all enclosures are being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Date: May 26, 2000

Type or Print Name of Person Mailing: Gail Ohlsson

*Gail Ohlsson*  
Signature of Person Mailing

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached Form PTO-1449 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application.

I. Timing of the Information Disclosure Statement:

This Information Disclosure Statement:

☐ Accompanies the new patent application submitted herewith. 37 CFR § 1.97(a).

☐ Is filed within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 CFR § 1.491.

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☒ As far as is known to the undersigned, is filed before the mailing date of a first Office Action on the merits. In the event, however, that an Office Action has crossed in the mail with this Information Disclosure Statement, the Commissioner is hereby authorized to charge Deposit Account No. 50-1189 for any fees required pursuant to 37 CFR §§ 1.17(p) or 1.17(i)(1).

☐ Is filed after the first office action and more than three months after the application's filing date or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance, whichever occurs first, and the Commissioner is hereby authorized to charge Deposit Account No. 50-1189 (Order No. 14918-725 CON4) for the fee (\$240) set forth in 37 CFR § 1.17(p) and any additional required fees.

☐ Is filed after the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by the fee (\$130) set forth in 37 CFR § 1.17(i)(1) and a certification as specified in 37 CFR § 1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the information disclosure statement.

*If either of the two immediately preceding paragraphs above referring to a certification are checked, the following "certification" under 37 CFR § 1.97(e) may need to be completed.* The undersigned certifies that:

☐ Each item of information contained in the information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.

☐ No item of information contained in this information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this information disclosure statement.

## II. Copies of the Cited Items:

☐ Copies of all of the items listed on the attached Form PTO-1449 are enclosed.

☐ Copies of only the following items listed on the attached Form PTO-1449 are enclosed:

☒ Copies of those items which are marked with an asterisk (\*) in the attached Form PTO-1449 are not supplied because they were previously cited by or submitted to the Office in a prior Application No. 08/226,162, filed April 11, 1994 (now Patent No. 5,674,984) and relied upon in this application for an earlier filing date under 35 U.S.C. § 120, which is a

divisional of 08/101,669 filed on August 2, 1993 (now abandoned), which is a continuation of 07/834,735 filed February 13, 1992 (now abandoned), which is a divisional of 07/504,785 filed April 3, 1990 (now abandoned). See 37 C.F.R. § 1.98(d).

[ ] Copies of those items which are marked with a double asterisk (\*\*) in the attached Form PTO-1449 are not supplied because they are U.S. patent application(s) and no copy of a U.S. patent application needs to be provided pursuant to 37 C.F.R. § 1.98(a)(2)(iii).

### III. Concise Explanation of Relevance:

[ ] A concise explanation of relevance of the items listed on Form PTO-1449 is not given.

[ ] A concise explanation of relevance of [some of] the items listed on Form PTO-1449 is in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references [copy attached].

[X] A concise explanation of relevance of the items listed on form PTO-1449 is given for only non-English language listed item(s). Specifically, the following foreign-language documents are being brought to the attention of the Examiner along with a concise explanation of the relevance of each document, as it is presently understood by the individual designated in 37 C.F.R. § 1.56(c) most knowledgeable about the content of the information in each document:

Reference B10 has been cited in the Japanese counterpart (App. No. 506683/1991) to the present application as relevant to Claims 19-21.

### IV. Conclusion:

Citation of the above documents shall not be construed as:

1. an admission that the documents are necessarily prior art with respect to the instant invention;
2. a representation that a search has been made, other than as described above; or
3. an admission that the information cited herein is, or is considered to be, material to patentability as defined in § 1.56(b).

It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO 1449 with initials or other appropriate marks.

The Commissioner is hereby authorized to charge Deposit Account No. 50-1189 for any additional fees required in connection with the filing of this Information Disclosure Statement.

Please address all correspondence regarding this communication to the following address:

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Dated: May 26, 2000

Respectfully submitted,

McCutchen, Doyle, Brown & Enersen, LLP

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**LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT(S)' INFORMATION DISCLOSURE  
STATEMENT**

14918-725 CON4

09/103,262

(Use several sheets if necessary)

## APPLICANT

Phillip W. Berman et al.

## FILING DATE

June 23, 1998

## GROUP ART UNIT

1643



## REFERENCE DESIGNATION

## U.S. PATENT DOCUMENTS

EXAM'R INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	Subclass	Filing Date If Appropriate
	A1*	4,725,669	2/88	Essex et al.	530	322	
	A2*	5,166,050	11/92	Shriver et al.	435	5	
	A3						
	A4						
	A5						
	A6						
	A7						
	A8						
	A9						
	A10						

## FOREIGN PATENT DOCUMENTS

EXAM'R INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	Subclass	TRANSLAT'N	
							yes	no
	B1*	33320/89	11/89	Australia				
	B2*	65235/90	4/91	Australia				
	B3*	187041	9/86	Europe				
	B4*	0 339 504 A2	11/88	Europe				

## OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)

C1*	Allan et al., "Major glycoprotein antigens that induce antibodies in AIDS patients are encoded by HTLV-III" <i>Science</i> 228 (4703):1091-1094 (May 1985).
C2*	Anderson et al., "Effect of Dose and Immunization Schedule on Immune Response of Baboons to Recombinant Glycoprotein 120 of HIV-1," <i>Jour. of Infectious Diseases</i> , 160(6):960-969 (1989).
C3*	Arthur et al., "Challenge of Chimpanzees (Pan troglodytes) Immunized with Human Immunodeficiency Virus Envelope Glycoprotein gp120," <i>Jour. of Virology</i> 63(12):5046-5053 (1989).

EXAMINER

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	A11						
	A12						
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**FOREIGN PATENT DOCUMENTS**

EXAM'R INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	Subclass	TRANSLATN	
							yes	no
	B5*	0 335 635 A1	10/89	Europe				
	B6*	WO 89/12095	12/89	PCT				
	B7*	WO 90/02196	3/90	PCT				
	B8*	WO 91/13906	9/91	PCT				

**OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)**

C4*	Barin et al., "Virus Envelope Protein of HTLV-III Represents Major Target Antigen for Antibodies in AIDS Patients," <i>Science</i> 228:1094-1096 (1985).
C5*	Barrett et al., "Large-Scale Production and Purification of a Vaccinia Recombinant-Derived HIV-1 gp160 and Analysis of Its Immunogenicity," <i>AIDS Research and Human Retroviruses</i> 5(2):159-171 (1989).
C6*	Berman et al., "Expression and Immunogenicity of the Extracellular Domain of the Human Immunodeficiency Virus Type 1 Envelope Glycoprotein, gp160" <i>Jour. of Virology</i> 63(8):3489-3498 (1989).

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## FOREIGN PATENT DOCUMENTS

EXAM'R INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	Subclass	TRANSLATN	
							yes	no
	B9*	WO 93/20104	10/93	PCT				
	B10	120284/1989	1989	Japan				
	B11							
	B12							

## OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)

C7*	Berman et al., "Human immunodeficiency virus type 1 challenge of chimpanzees immunized with recombinant envelope glycoprotein gp120" <i>Proc. Natl. Acad. Sci. USA</i> 85:5200-5204 (1988).
C8*	Berman et al., "Protection from Genital Herpes Simplex Virus Type 2 Infection by Vaccination with Cloned Type 1 Glycoprotein D," <i>Science</i> 227:1490-1492 (1985).
C9*	Berman et al., "Protection of Chimpanzees From Infection by HIV-1 After Vaccination With Recombinant Glycoprotein gp120 but not gp160," <i>Nature</i> 345:622-625 (1990).

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	A31						
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EXAM'R INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	Subclass	TRANSLATN	
							yes	no
	B13							
	B14							
	B15							
	B16							

**OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)**

	C10*	Celltech "CHO cell rgp120" <i>Certificate of Analysis</i> pp.1-2 (Jan., 1990).
	C11*	Chakrabarti et al., "Expression of the HTLV-III envelope Gene by a Recombinant Vaccinia Virus," <i>Nature</i> 320:535-540 (1986).
	C12*	Clements et al., "The V3 Loops of the HIV-1 and HIV-2 Surface Glycoproteins Contain Proteolytic Cleavage Sites; A Possible Function in Viral Fusion" <i>AIDS Research and Human Retroviruses</i> 7:3-16 (1991).

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	A41						
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							yes	no
	B17							
	B18							
	B19							
	B20							

**OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)**

C13*	Desrosiers et al., "Vaccine protection against simian immunodeficiency virus infection," <i>Proc. Natl. Acad. Sci. USA</i> 86:6353-6357 (1989).
C14*	Fahey et al., "Status of immune-based therapies in HIV infection and AIDS," <i>Clin. exp. Immunol.</i> 88:1-5 (1992).
C15*	Fauci et al., "Development and Evaluation of a Vaccine for Human Immunodeficiency Virus (HIV) Infection," <i>Annals of Internal Med.</i> 110(5):373-385 (1989).

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	A51						
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## FOREIGN PATENT DOCUMENTS

EXAM'R INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	Subclass	TRANSLAT'N	
							yes	no
	B21							
	B22							
	B23							
	B24							

## OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)

C16*	Fox, J.L., "No Winners Against AIDS," <i>Bio/Technology</i> 12:128 (Feb. 1994).
C17*	Homsy et al., "The Fc and Not CD4 Receptor Mediates Antibody Enhancement of HIV Infection in Human Cells," <i>Science</i> 244:1357-1360 (1989).
C18*	Hu et al., "Effect of Immunization With a Vaccinia-HIV env Recombinant on HIV Infection of Chimpanzees," <i>Nature</i> 328:721-723 (1987).

## EXAMINER

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FORM PTO-1449 (Modified)

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	A61						
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EXAM'R INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	Subclass	TRANSLAT'N	
							yes	no
	B25							
	B26							
	B27							
	B28							

## OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)

C19*	Hu et al., "Expression of AIDS virus envelope gene in recombinant vaccinia viruses," <i>Nature</i> 320:537-540 (1986).
C20*	Jahaverian et al., "Principal neutralizing domain of the human immunodeficiency virus type 1 envelope protein," <i>Proc. Natl. Acad. Sci. USA</i> 86:6768-6772 (1989).
C21*	Kitchen et al., "Aetiology of AIDS - antibodies to human T-cell leukaemia virus (type III) in haemophiliacs," <i>Nature</i> 312:367-369 (1984).

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							yes	no
	B29							
	B30							
	B31							
	B32							

## OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)

C22*	Krust et al., "Characterization of a monoclonal antibody specific for the HIV-1 precursor glycoprotein," <i>AIDS</i> 2:17-24 (1988).
C23*	Lasky, Laurence A., "Current Status of the Development of an AIDS Vaccine," <i>Crit. Revs. in Immunology</i> 9(3):153-172 (1989).
C24*	Lasky et al., "Delineation of a Region of the Human Immunodeficiency Virus Type 1 gp120 Glycoprotein Critical for Interaction with the CD4 Receptor," <i>Cell</i> 50:975-985 (1987).

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	A81						
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							yes	no
	B33							
	B34							
	B35							
	B36							

## OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)

C25*	Lasky et al., "Neutralization of the AIDS Retrovirus by Antibodies to a Recombinant Envelope Glycoprotein," <i>Science</i> 233:209-212 (1986).
C26*	Letvin et al., "AIDS-like Disease in Macaque Monkeys Induced By Simian Immunodeficiency Virus: A Vaccine Trial," <i>Vaccines</i> 87:209-213 (1987).
C27	Liou, Ruey-Shyan et al., "A Chimeric Mouse-Human Antibody That Retains Specificity For HIV gp120 And Mediates The Lysis of HIV-Infected Cells," <i>Journal of Immunology</i> 143:3967-3975 (Dec. 1989).

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							yes	no
	B37							
	B38							
	B39							
	B40							

## OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)

C28*	Looney et al., "Type-Restricted Neutralization of Molecular Clones of Human Immunodeficiency Virus," <i>Science</i> 241:357-359 (1988).
C29*	Matsushita et al., "Characterization of a Human Immunodeficiency Virus Neutralizing Monoclonal Antibody and Mapping of the Neutralizing Epitope," <i>Jour. of Virology</i> 62(6):2107-2114 (1988).
C30*	Modrow et al., "Computer-Assisted Analysis of Envelope Protein Sequences of Seven Human Immunodeficiency Virus Isolates: Prediction of Antigenic Epitopes in Conserved and Variable Regions," <i>Jour. of Virology</i> 61(2):570-578 (1987).

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(Information Disclosure Statement — Section 9 PTO-1449 (Modified) [6-1])

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							yes	no
	B41							
	B42							
	B43							
	B44							

## OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)

C31*	Murphy-Corb et al., "A Formalin-Inactivated Whole SIV Vaccine Confers Protection in Macaques," <i>Science</i> 2:1293-1297 (1989).
C32*	Newmark, Peter, "Receding Hopes of AIDS vaccines," <i>Nature</i> 333:699 (1988).
C33*	Palker et al., "Type-specific neutralization of the human immunodeficiency virus with antibodies to env-encoded synthetic peptides," <i>Proc. Natl. Acad. Sci. USA</i> 85:1932-1936 (1988).

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(Use several sheets if necessary)

**ATTY. DOCKET NO.**

14918-725 CON4

**SERIAL NO.**

09/103,262

**APPLICANT**

Phillip W. Berman et al.

**FILING DATE**

June 23, 1998

**GROUP ART UNIT**

1643

**REFERENCE DESIGNATION****U.S. PATENT DOCUMENTS**

EXAM'R INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	Subclass	Filing Date If Appropriate
	A111						
	A112						
	A113						
	A114						
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	A118						
	A119						
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**FOREIGN PATENT DOCUMENTS**

EXAM'R INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	Subclass	TRANSLAT'N	
							yes	no
	B45							
	B46							
	B47							
	B48							

**OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)**

C34*	Prince et al., "Failure of a Human Immunodeficiency Virus (HIV) Immune Globulin to Protect Chimpanzees Against Experimental Challenge With HIV," <i>Proc. Natl. Acad. Sci. USA</i> 85:6944-6948 (1988).
C35*	Robey et al., "Prospect for prevention of human immunodeficiency virus infection: Purified 120-kDa envelope glycoprotein induces neutralizing antibody," <i>Proc. Natl. Acad. Sci.</i> 83:7023-7027 (1986).
C36*	Robey, W.G. et al., "Characterization of envelope and core structural gene products of HTLV-III with sera from AIDS patients," <i>Science</i> 228 (4699):593-595 (May 3, 1985).

**EXAMINER****DATE CONSIDERED**

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	A121						
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## FOREIGN PATENT DOCUMENTS

EXAM'R INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	Subclass	TRANSLATN	
							yes	no
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## OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)

C37*	Robinson, Jr. et al., "Antibody-Dependent Enhancement of Human Immunodeficiency Virus Type 1 Infection," <i>The Lancet</i> 790-794 (1988).
C38*	Robinson, Jr. et al., "Human Monoclonal Antibodies to the Human Immunodeficiency Virus Type 1 (HIV-1) Transmembrane Glycoprotein gp41 Enhance HIV-1 Infection <i>in vitro</i> ," <i>Proc. Natl. Acad. Sci. USA</i> 87:3185-3189 (1990).
C39*	Rusche et al., "Antibodies That Inhibit Fusion of Human Immunodeficiency Virus-infected Cells Bind a 24-amino Acid Sequence of the Viral Envelope, gp120," <i>Proc. Natl. Acad. Sci. USA</i> 85:3198-3202 (1988).

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FORM PTO-1449 (Modified)  <b>LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT(S)' INFORMATION DISCLOSURE STATEMENT</b> (Use several sheets if necessary)	<b>ATTY. DOCKET NO.</b>  14918-725 CON4	<b>SERIAL NO.</b>  09/103,262
	<b>APPLICANT</b> Phillip W. Berman et al.	
	<b>FILING DATE</b> June 23, 1998	<b>GROUP ART UNIT</b> 1643

**REFERENCE DESIGNATION U.S. PATENT DOCUMENTS**

EXAM'R INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	Subclass	Filing Date If Appropriate
	A131						
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EXAM'R INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	Subclass	TRANSLATN	
							yes	no
	B53							
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**OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)**

C40*	Salk et al., "Control of Influenza and Poliomyelitis with Killed Virus Vaccines," <i>Science</i> 195:834-847 (1977).
C41*	Salk, Jonas, "Prospects for the Control of AIDS by Immunizing Seropositive Individuals," <i>Nature</i> 327:473-476 (1987).
C42*	Stephens et al., "A chink in HIV's armour?" <i>Nature</i> 343:219 (1990).

EXAMINER	DATE CONSIDERED
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	A141						
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							yes	no
	B57							
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## OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)

C43	Thiriart, Clotilde et al., "Several Antigenic Determinants Exposed on the gp120 Moiety of HIV-1 gp160 Are Hidden on the Mature gp120," <i>Journal of Immunology</i> 143:1832-1836 (Sept., 1989)
C44*	Vandenbark et al., "Immunization with a Synthetic T-cell Receptor V-region Peptide Protects Against Experimental Autoimmune Encephalomyelitis," <i>Nature</i> 341:541-544 (1989).
C45*	Van Eendenburg et al., "Cell-Mediated Immune Proliferative Responses to HIV-1 of Chimpanzees Vaccinated With Different Vaccinia Recombinant Viruses," <i>Aids Res. and Human Retroviruses</i> 5(1):41-50 (1989).

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	A151						
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							yes	no
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	B62							
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## OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)

C46*	Veronese et al., "Characterization of gp41 As the Transmembrane Protein Coded by the HTLV-III/LAV-Envelope Gene" <i>Science</i> 229:1402-1405 (1985).
C47	Yoshida, Nobuko et al., "Metacyclic Neutralizing Effect of Monoclonal Antibody 10D8 Directed to the 35- and 50-Kilodalton Surface Glycoconjugates of <i>Trypanosoma cruzi</i> ," <i>Infection and Immunity</i> 57:6:1663-1667 (June 1989).
C48*	Zagury et al., "Immunization Against AIDS in Humans," <i>Nature</i> 326:249-250 (1987).

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	B63							
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## OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)

C49*	Zagury et al., "A group specific anamnestic Immune Reaction Against HIV-1 Induced by a Candidate Vaccine Against AIDS," <i>Nature</i> 332:728-731 (1988).
C50*	Zarling et al., "T-cell responses to human AIDS virus in Macaques Immunized With Recombinant Vaccinia Viruses," <i>Nature</i> 323:344-346 (1986).

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